OCT 21 2002 K023245

510(k) SUMMARY

Summary of Safety and Effectiveness for the Blood Flow Analyzer

Submitter:

Paradigm Medical Industries, Inc.
2355 South 1070 West
Salt Lake City, Utah 84119
Phone: 801-977-8970 Fax: 801-977-8973
Contact Person: David M. Silver
Summary Preparation Date: September 25, 2002

Device:

Trade Name:	Blood Flow Analyzer (BFA)
Common Names:	Tonometer and Accessories, Blood Flow Analyzer
Classification Name:	886.1930 - Tonometer, AC Powered
Product Code:	86 NJJ - Tonometer, Analyzer, Ocular Blood Flow

Legally Marketed Predicate Device:

K970887, Blood Flow Analyzer (BFA), Paradigm Medical Industries, Inc.

Establishment Registration Number: 1722205

Description of Device:

The Paradigm Medical Industries, Inc. Blood Flow Analyzer (BFA) is an electronic pneumatic tonometer capable of measuring and recording the intraocular pressure. The pressure measurements are made at a rate of 200 times per second over a period of 5-15 seconds. Contact with the eye is by means of a sterilized single-use per patient probe having an integral membrane that isolates the cornea from the internal pneumatic operation of the BFA. The pulsatile ocular blood flow is derived from the intraocular pressure measurements

acquired with the pneumatic tonometer using mathematical equations that link intraocular pressure to ocular volume change and volume flow.

The Blood Flow Analyzer (BFA) measures intraocular pressure with a high frequency response. The observed oscillations in pressure occur as a result of accommodating changes in the intraocular blood volume induced by the arterial blood pulse. The fundamental phenomenon can be gleaned by considering periodic bolus flow. As a bolus of blood enters the eye through the ophthalmic arterial system, the eye will expand. Since the fluid is incompressible and the eye is an elastic chamber, the eye will expand in volume in an amount that is equal to the volume of the blood that is entering the eye. Simultaneously, blood is escaping from the eye through the venous system, but at a rate that is slower than the incoming bolus. During the interval between boluses, the venous continues to drain. The inflow of fluid to the eye chamber is greater than the outflow for parts of each cardiac cycle and the inflow is less than the outflow during other parts of the cycle. Clearly the average inflow must equal the outflow rate. Thus, the net flow into the chamber is positive during periods of above average inflow, and is negative when inflow is less than average. The volume of the eye expands during periods of positive net flow, and contracts when the net flow is negative. Because of the elastic nature of the corneal-scleral shell of the eye, as the volume of the eye fluctuates with the cardiac cycle, the intraocular pressure will fluctuate in direct response to the volume changes. Therefore, the intraocular pressure is physiologically related to the volume and volume change in the eye. The linkage between pressure and volume is the pressure-volume relation. The pressure-volume relation was derived by analyzing the pressure responses to injections of volumes of fluid to living human eyes measured by direct cannulation of the eye connected to a manometer.

Definition and Calculation of Parameters:

TONOMETRY: The BFA is fundamentally a tonometer, using a pneumatic mode of operation. To measure the intraocular pressure, the instrument utilizes a probe that is a sterilized single-use per patient accessory. The probe tip is manufactured with an integral membrane that separates the tonometer's pneumatic air flow from the cornea. The BFA acquires the intraocular pressure of the eye 200 times per second and electronically captures the pressure readings in its computer memory. The BFA is capable of performing all of the standard, classic tonometric measurements, tonographic procedures and tonometric provocative tests. In addition, the BFA intraocular pressure measurement provides a value for the maximum intraocular pressure per pulse, the minimum intraocular pressure per pulse, and the average intraocular pressure per pulse. The difference between the maximum and minimum intraocular pressures per pulse is the amplitude of the intraocular pressure per pulse (Pulse Amplitude).

PULSATILE OCULAR BLOOD VOLUME: Using the pressure-volume relation and the BFA intraocular pressure measurements permits the calculation

of the change in volume of the eye sampled at 200 times per second. For each cardiac pulse, the difference between the minimum volume and the maximum volume during the pulse is the amplitude of the volume change for that pulse. The amplitude of the volume change per pulse is the pulsatile ocular blood volume (Pulse Volume).

PULSATILE OCULAR BLOOD FLOW: Over a single cardiac cycle, the pulsatile ocular blood flow rises rapidly to a peak value at systole and then falls usually somewhat more slowly to a minimum value at diastole. The average pulsatile ocular blood flow is obtained from the pulsatile ocular blood flow curve as the average of the inflow during each pulse multiplied by the number of pulses per second. The reproducibility of the BFA pulsatile ocular blood flow measurement has been assessed using the method of repeated measures on normal healthy volunteers. The reliability of the BFA pulsatile ocular blood flow measurement has been further confirmed using test-retest repeated measurements on normal patients showing that variation in bias and first exposure effect were not significant. The pulsatile ocular blood flow result is presented in microliters per second or microliters per minute (user's choice).

PULSATILITY INDEX EQUIVALENT (PEQ): Gosling defined the pulsatility index (PI) in terms of the waveform of fluid velocity in vessels to be PI = (Peak to Peak)/Mean, where peak to peak is the magnitude of difference between the maximum and minimum velocity during a pulse cycle and mean is the mean value of the velocity during the pulse cycle. Color Doppler Imaging techniques can compute this quantity in terms of velocities. The BFA has actual net flow values (not just velocities) and therefore the "pulsatility index" is not computed relative to velocities. Instead, a "pulsatility index equivalent" is computed, where the word "equivalent" is used to denote that the concept is similar to the pulsatility index except that flow is used instead of velocity. The BFA calculates the peak to peak difference in flow and the mean flow from its pulsatile ocular blood flow curve and then performs the quotient (Peak to Peak)/Mean to produce the pulsatility index equivalent.

Study Protocol for Normative Pulsatile Ocular Blood Flow:

A protocol and patient questionnaire were used to obtain data for determining the normative pulsatile ocular blood flow in males and females. The study was conducted at six optometric centers in the United Kingdom in 1995 and sponsored by OBF Labs (UK), Ltd. The definition for "normal" is a patient that answered all five questions of the patient questionnaire in the negative. Therefore the "normal" patient will have no family history of glaucoma, will have no significant ocular history (ocular diseases, ocular treatments or previous ocular surgery), will have no use of ocular medications, will have no significant medical history (systemic hypertension, diabetes, or vascular disease), and will have no use of systemic beta blockers. The overall sample size was 1502, with 777 subjects satisfying the inclusion criteria to be considered normal. The

normative data set was analyzed at Moorfields Eye Hospital, London and was referred to as "normal controls" for comparison of pulsatile ocular blood flow in asymmetric normal tension glaucoma and normal subjects.

Changes Between The Blood Flow Analyzer Cleared Under K970887 And The Blood Flow Analyzer That Is The Subject of This 510(k) Submission:

The differences in the device from K970887 to this present submission are mainly cosmetic. Briefly, the changes were: outer casing, LCD screen, button color, pump (from a 12 psi to 20 psi), and software changes. These changes were incorporated into the device utilizing documented procedures. Paradigm is in substantial compliance with 21 CFR Part 820 and is an ISO 9001/EN 46001/EN13485 Certified manufacturing facility.

Intended Use of the Device:

The intended Indications for Use for the Blood Flow Analyzer are: Tonometry for Measuring and Recording Intraocular Pressures and Intraocular Pressure Pulse Amplitudes, Pulsatile Ocular Blood Flow, Pulsatile Ocular Blood Volume, Pulsatility Index Equivalent (PEQ).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2002

Paradigm Medical Industries, Inc.
c/o David M. Silver, Ph.D; Director
2355 South 1070 West
Salt Lake City, Utah 84119

Re: K023245
Trade Name: Blow Flow Analyzer (BFA)
Classification Regulation Number: 886.1930
Regulation Name: Tonometer
Regulatory Class: II
Product Code: NJJ
Dated: September 30, 2002
Received: September 30, 2002

Dear Dr. Silver:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K023245

Device Name: Blood Flow Analyzer (BFA)

Indications For Use:

Tonometry for Measuring and Recording Intraocular Pressures and Intraocular Pressure Pulse Amplitudes

Pulsatile Ocular Blood Flow

Pulsatile Ocular Blood Volume

Pulsatility Equivalence Index (PEQ)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Yvonne T. Dean

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K023245

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)